UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

TATIANA KOROLSHTEYN, on behalf of herself and all others similarly situated, Plaintiff, v. COSTCO WHOLESALE CORPORATION and NBTY, INC., Defendants.	Case No.: 3:15-cv-709-CAB-RBB **ORDER GRANTING MOTION FOR SUMMARY JUDGMENT** [Doc. Nos. 172, 173, 176, 177, 178, 183, 184, 187, 191]

This matter is before the Court on Defendants' motion for summary judgment. The motion has been fully briefed, and the Court held a hearing on August 8, 2017. As discussed below, the motion is granted.

I. Background

This case arises out of alleged false statements on the labels of TruNature Gingko Biloba with Vinpocetine ("TruNature Gingko"), which is manufactured by Defendant NBTY, Inc. ("NBTY") and sold at the stores of Defendant Costco Wholesale Corporation ("Costco"). The labels of TruNature Gingko represent that the product "supports alertness & memory," that "Gingko biloba can help with mental clarity and memory," and that "[i]t

also helps maintain healthy blood flow to the brain to assist mental clarity and memory, especially occasional mild memory problems associated with aging" (collectively, the "Label Claims"). [Doc. No. 100 at ¶ 1.] According to the third amended complaint (the "TAC"), these representations are false because studies show that Gingko biloba and vinpocetine do not provide any mental clarity, memory or mental alertness benefits. [*Id.* at ¶ 2.]

Lead Plaintiff Tatiana Korolshteyn alleges she bought a bottle of TruNature Gingko based on the allegedly false representations on the product label and filed this lawsuit on behalf of herself and a class of consumers who purchased TruNature Gingko in California. The TAC asserts two claims: (1) violation of California's unfair competition law (the "UCL"), California Business & Professions Code § 17200 *et seq.*; and (2) violation of California's Consumer Legal Remedies Act ("CLRA"), California Civil Code § 1750 *et seq*. The prayer for relief asks for restitution and disgorgement of Defendants' revenues, actual, statutory and punitive damages, and attorneys' fees and costs. [*Id.* at 15.]

On March 16, 2017, the Court granted Plaintiff's motion to certify a class consisting of "all California consumers who, within the applicable statute of limitations, purchased TruNature Gingko Biloba with Vinpocetine until the date notice is disseminated." [Doc. No. 158 at 14.] Defendants now move for summary judgment. Also pending before the Court are motions by both sides to exclude evidence and testimony from the other side's experts, a motion from Plaintiff to strike Defendants' citation to certain evidence in connection with their summary judgment motion, and a motion by The Council for Responsible Nutrition ("CRN") for leave to file an amicus brief. This opinion addresses each motion in turn.

II. Motion for Leave to File a Brief Amicus Curiae [Doc. No. 187]

CRN has filed a motion for leave to file an amicus curiae brief, along with the proposed brief itself. "The district court has broad discretion to appoint amici curiae." *Safari Club Int'l v. Harris*, No. 2:14-CV-01856-GEB-AC, 2015 WL 1255491, at *1 (E.D. Cal. Jan. 14, 2015) (quoting *Hoptowit v. Ray*, 682 F.2d 1237, 1260 (9th Cir. 1982)). "An

amicus brief should normally be allowed when, among other considerations, the amicus has unique information or perspective that can help the court beyond the help that the lawyers for the parties are able to provide." *Missouri v. Harris*, No. 2:14-CV-00341-KJM, 2014 WL 2987284, at *2 (E.D. Cal. July 1, 2014) (internal quotation marks and citation omitted). "While historically, amicus curiae is an impartial individual who suggests the interpretation and status of the law, gives information concerning it, and advises the Court in order that justice may be done, rather than to advocate a point of view so that a cause may be won by one party or another, the Ninth Circuit has said there is no rule that amici must be totally disinterested." *Id.* (internal quotation marks and citations omitted).

Here, Plaintiff's primary argument for denying CRN's motion is that CRN's brief "is highly partisan and heavily influenced by its own self-interest in Defendants' position." [Doc. No. 206 at 2.][1] The Court disagrees. Nature's Bounty (presumably an affiliate of Defendant NBTY) is one of CRN's 116 members, and there is little doubt that CRN has an interest in the outcome of this case, but it is unlikely any amicus would be totally disinterested in the outcome of a case because otherwise one would not bother to incur the expense of filing a brief. Moreover, notwithstanding its interest, CRN's brief focuses entirely on the law applicable to Plaintiff's false advertising claims and does not argue expressly that Defendants should win summary judgment (although Plaintiff appears to concede that CRN's interpretation of the law would yield that result). In other words, CRN is not impartial, but its brief simply "suggests the interpretation and status of the law, gives information concerning it, and advises the Court in order that justice may be done, rather than to advocate a point of view so that a cause may be won by one party or another." *Harris*, 2014 WL 2987284, at *2. Accordingly, CRN's motion to file an amicus brief is granted.

[1] Pinpoint page citations to documents in the record are to the ECF page number at the top of the page.

III. Legal Standard for Summary Judgment

A party is entitled to summary judgment "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). To avoid summary judgment, disputes must be both 1) material, meaning concerning facts that are relevant and necessary and that might affect the outcome of the action under governing law, and 2) genuine, meaning the evidence must be such that a reasonable jury could return a verdict for the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *Cline v. Indus. Maint. Eng'g & Contracting Co.*, 200 F.3d 1223, 1229 (9th Cir. 2000).

The initial burden of establishing the absence of a genuine issue of material fact falls on the moving party. *See Celotex Corp.*, 477 U.S. at 323. If the moving party can demonstrate that its opponent has not made a sufficient showing on an essential element of his case, the burden shifts to the opposing party to set forth facts showing that a genuine issue of disputed fact remains. *Id.* at 324. When ruling on a summary judgment motion, the court must view all inferences drawn from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). However, "[t]he district court need not examine the entire file for evidence establishing a genuine issue of fact, where the evidence is not set forth in the opposing papers with adequate references so that it could conveniently be found." *Carmen v. San Francisco Unified Sch. Dist.*, 237 F.3d 1026, 1031 (9th Cir. 2001).

IV. Legal Standards for UCL and CLRA Claims Based on Allegedly False Efficacy Claims on Product Labels

The majority of the parties' arguments on summary judgment, as well as their arguments for exclusion of expert testimony, involve what Plaintiff must prove to succeed on her false advertising claims under the UCL and CLRA. Plaintiff appears to concede that her claim does not survive under the standards advocated by Defendants. For their

part, Defendants argue that summary judgment is appropriate even under the standards argued by Plaintiff.

The UCL prohibits any "unlawful, unfair or fraudulent business act or practice [in addition to any] unfair, deceptive, untrue or misleading advertising . . . ." Cal. Bus. & Prof. Code §§ 17200, 17500. The CLRA prohibits "unfair methods of competition and unfair or deceptive acts or practices." Cal. Civ. Code § 1770. Claims under either the UCL or CLRA are governed by the "reasonable consumer" test, which requires plaintiffs to prove that "members of the public are likely to be deceived." *Williams v. Gerber Prods. Co.*, 552 F.3d 934, 938 (9th Cir. 2008) (citing *Freeman v. Time, Inc.*, 68 F.3d 285, 289 (9th Cir. 1995)). The UCL and CLRA prohibit "not only advertising which is false, but also advertising which although true, is either actually misleading or which has the capacity, likelihood or tendency to deceive or confuse the public." *Kasky v. Nike, Inc.*, 27 Cal. 4th 939, 951 (2002). Thus, "[a] perfectly true statement couched in such a manner that it is likely to mislead or deceive the consumer, such as by failure to disclose other relevant information, is actionable" under the UCL. *Day v. AT & T Corp.*, 63 Cal. App. 4th 325, 332–33 (1998).

In a false advertising case under the UCL and CLRA, the plaintiff "bears the burden of proving that the defendant's advertising claim is false or misleading." *Nat'l Council Against Health Fraud, Inc. v. King Bio Pharm., Inc.*, 107 Cal. App. 4th 1336, 1341, 1344 (Cal. Ct. App. 2003); *see also Kwan v. SanMedica Int'l*, 854 F.3d 1088, 1096 (9th Cir. 2017) ("King Bio's holding is firmly established law in California."). "Private plaintiffs are not authorized to demand substantiation for advertising claims." *King Bio.*, 107 Cal. App. 4th at 1345. Only prosecuting authorities "have the administrative power to request advertisers to substantiate advertising claims. . . ." *Id.* at 1344. "The rationale behind the legislation regarding substantiation claims is to provide prosecuting authorities a means of protecting consumers while limiting 'undue harassment of advertisers and is the least burdensome method of obtaining substantiation for advertising claims.'" *Kwan*, 854 F.3d at 1097-98 (quoting *King Bio.*, 107 Cal. App. at 1345).

In *King Bio*, the California Court of Appeals held that "falsity of the advertising claims may be established by testing, scientific literature, or anecdotal evidence," *King Bio.*, 107 Cal. App. 4th at 1348. However, this standard leaves open the question of how or whether a plaintiff can prove falsity when a defendant offers scientific evidence and admissible expert testimony supporting an advertising claim about the efficacy of the product in question. There is no controlling Ninth Circuit authority on this issue, and other courts' interpretation and application of the proscription on lack of substantiation claims by private plaintiffs have varied.

In *In re GNC Corp.*, 789 F.3d 505, 510 (4th Cir. 2015), a Fourth Circuit case that included claims under the UCL and CLRA, the plaintiffs alleged in their complaint that health representations made on the products' packaging were false because "the vast weight of competent and reliable scientific evidence" showed that the ingredients in the product did not provide the promised health benefits. The complaint also cited a number of peer-reviewed published studies that supported this argument. *In re GNC Corp.*, 789 F.3d at 510. The court, however, held that "to state a false advertising claim on a theory that representations have been proven to be false, plaintiffs must allege that all reasonable experts in the field agree that the representations are false. If plaintiffs cannot do so because the scientific evidence is equivocal, they have failed to plead that the representations based on this disputed scientific evidence are false." *Id.* at 516. Notably, Plaintiff does not argue that she can satisfy this standard, asserting only that this case is not the law in the Ninth Circuit. [Doc. No. 189 at 23-24.] Plaintiff, however, does not cite to any Ninth Circuit or California state court cases that have rejected *In re GNC*.[2]

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[2] Plaintiff cites one district court case that found *In re GNC* insufficient to cause it to reconsider a prior decision denying a motion to dismiss. *Zakaria v. Gerber Prods Co.*, Case No. LA CV15-00200 JAK(Ex), 2015 WL 4379743 (C.D. Cal. Jul. 14, 2015). The holding in *Zakaria*, a non-binding opinion on California state law, that *In re GNC* does not constitute an "intervening change in controlling law" as required to reconsider a decision (*Smith v. Clark Cty Sch. Dist.*, 727 F.3d 950, 955 (9th Cir. 2013)), does not mean *In re GNC* is not persuasive as to California's law on UCL and CLRA claims like the one before the Court here. Regardless, the undersigned respectfully disagrees with *Zakaria*'s disregard of *In re GNC* and

Several California district courts have addressed a plaintiff's burden of proving falsity in the face of scientific evidence from a defendant that supports the advertised efficacy claims. In the case on which Plaintiff primarily relies, and which Defendants and CRN ask the Court to reject, the district court held that a plaintiff who had alleged that advertising claims were false and misleading had "two lines of attack." *Mullins v. Premier Nutrition Corp.*, 178 F.Supp. 3d 867, 894 (N.D. Cal. 2016). She could prove that the advertising claims are "literally false if a reasonable jury concludes that all *reasonable* scientists agree," or that the claims are "*misleading* by showing that the vast weight of the competent evidence establishes that those health claims are false." *Id.* at 894-95 (*emphasis* in original). The *Mullins* opinion then notes that under this second line of attack, a plaintiff "can concede the existence of scientific studies substantiating a representation, but argue that those studies are poorly designed, incredible, or represent the view of a minority of scientists." *Id.* at 895.

The *Mullins* court ultimately denied summary judgment for two reasons. First, the court held that "because [the plaintiff] and her experts have offered principled, supported critiques of the studies [the defendant's expert] used to form his opinions, and a jury may reasonably adopt those same views, she may be able to convince a jury that [the defendant's] claims are literally false." *Id.* at 896. Second, the court held that a jury could conclude that the efficacy claims were misleading if "the totality of the evidence" supports the conclusion that the product does not work as advertised. *Id.* at 894. Thus, according to the *Mullins* court, summary judgment was not appropriate because a jury could believe,

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general analysis of the burdens of a plaintiff alleging false advertising based on alleged misrepresentations about a products' efficacy. In particular, as discussed herein, the Court disagrees with *Zakaria*'s holding that "[i]f some reasonable experts incorrectly had opined that [the product] had [the advertised health benefit], this would not necessarily bar the claim. A fact issue could remain as to what Defendant knew as to this scientific issue, including any contrary scientific opinions." 2015 WL 4379743, at *3. To the contrary, if the evidence as to an advertising claim is equivocal, as would be the case if reasonable experts offer contradictory opinions on the truth or falsity of statements, a plaintiff cannot prove the falsity of the statements. Whether the defendant was aware that contrary scientific opinions exist is irrelevant to whether the plaintiff can maintain a false advertising claim.

based on the critiques by the plaintiff's experts, that "those studies finding positive results pale in comparison to those going the other way," rendering the efficacy claims misleading. *Id.* at 897.

Other district courts, however, have granted summary judgment when the defendants offer scientific evidence supporting their claims, notwithstanding arguments and critiques of the quality of the studies cited by the defendant. As one court noted, "[d]isputes over the quality and credibility of the substantiation for the claims on Defendants' products are not properly brought before the Court in a suit by private plaintiffs." *Reed v. NBTY, Inc.*, No. EDCV 13-0142 JGB (OPx), 2014 WL 12284044, at *14 (C.D. Cal. Nov. 18, 2014). Moreover, the *Reed* court held that even the existence of studies that find none of the advertised benefits in the product do not save a private plaintiff's false advertising claim because "[i]nconclusive findings and unsettled science are insufficient to meet Plaintiffs' burden of raising a question of fact on the issue of falsity," and "mixed evidence demonstrates at most that the science on [the product's] effectiveness is inconclusive." *Id.* at *14-15. Thus, "where there are studies demonstrating both the effectiveness and ineffectiveness of the Products, a reasonable jury could not find that the advertising claims are false." *Id.*; *cf. In re GNC*, 789 F.3d at 515 ("By characterizing this dispute as a battle of the experts, Plaintiffs highlight the [complaint's] concession that a reasonable difference of scientific opinion exists as to whether [the products] can provide the advertised [] health benefits.").

In another case involving similar claims of false advertisements about a Gingko biloba product, and in which the parties relied on some of the same studies they cite here, the court noted that "[t]aking issue with the strength or significance of the studies . . . is not enough to prove their falsity." *Sonner v. Schwabe N. Am., Inc.*, 2017 WL 474106, at *7, __ F.Supp. 3d __ (C.D. Cal. Feb. 2, 2017). The court granted summary judgment for the defendant, notwithstanding *Mullins*, holding that "Plaintiff's expert, if believed by a reasonable jury, demonstrates that Defendants' scientific substantiation for its product claims is not strongly substantiated. However, this does not establish a triable issue of fact

that Defendants' advertising claims are false or misleading." *Id.* at *8 (internal brackets, ellipses and citation omitted).

Although the outcomes in these cases differ, a common thread in all of them is that when a defendant presents scientific studies supporting its advertising claim, a plaintiff must do more than present its own studies that do not support the advertising claim, thereby demonstrating that evidence is equivocal. Where *Mullins* is the outlier is in its apparent determination that the question of whether the evidence is equivocal is for the jury, precluding summary judgment even where there are scientific studies on both sides of the issue.[3] In other words, the *Mullins* court appeared to hold that if a plaintiff offers "principled, supported critiques" of the defendant's studies, a jury can find that the defendant's studies are not in fact reasonable or scientific such that they effectively do not constitute evidence at all, making the advertised claim literally false. Alternatively, according to *Mullins*, a jury could find that because the plaintiff's studies are more persuasive, the advertising claims are misleading. *Id.* at 895. This rationale is difficult to reconcile with *King Bio*.

Under California law, to survive summary judgment on a false or misleading advertising claim, a plaintiff must present evidence sufficient to allow a jury to find: (1) that a statement is literally false; or (2) that the statement is literally true, but that it is misleading to a reasonable consumer. *See Kasky*, 27 Cal. 4th at 951; *cf. In re GNC*, 789 F.3d at 514 ("Courts uniformly interpret 'false or misleading' as creating two different theories of recovery in a false advertising claim: A plaintiff must allege either (i) that the challenged representation is literally false or (ii) that it is literally true but nevertheless

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[3] The *Mullins* opinion even contradicts itself on this point. At one point, the court states that "if the scientific record is equivocal, then summary judgment is appropriate because no reasonable jury could conclude that the representations are false or misleading." *Mullins*, 178 F.Supp. 3d at 893. Later on in the opinion, however, the court states: "Of course, a jury may also conclude that these studies muddy the waters enough to believe the scientific literature on the subject is equivocal, in which case it must side with [the defendant]." *Id.* at 897. If the existence of equivocal evidence makes summary judgment appropriate, then a jury cannot be the arbiter of whether the evidence is equivocal.

misleading."). Here, notwithstanding Plaintiff's arguments otherwise, Plaintiff is only alleging the former—that the Label Claims are literally false. Although the TAC alleges and Plaintiff argues on summary judgment that the Label Claims are "false and misleading," she is really alleging and arguing that the Label Claims are misleading *because they are false*. *See generally In re GNC*, 789 F.3d at 514 ("[S]tatements that are literally false are necessarily misleading . . ."); *Day*, 63 Cal. App. 4th at 332 (noting distinction between "those advertisements which have deceived or misled because they are untrue, [and] those which may be accurate on some level, but will nonetheless tend to mislead or deceive"). Plaintiff is not arguing that the Label Claims are literally true but misleading for some other reason. Doing so would undercut her literal falsity argument.

Whether the Label Claims are true or false is a binary choice—they are true, or they are false. When the scientific evidence is equivocal, it is impossible to prove that an advertised claim is either literally true or literally false. Thus, what Plaintiff is arguing, and what *Mullins* appears to support, is that the Label Claims are misleading or deceptive because there is insufficient evidence supporting them or because the contradictory evidence is stronger. A similar argument was rejected by Judge Battaglia in *Johns v. Bayer Corp.*, No. 09CV1935 AJB DHB, 2013 WL 1498965 (S.D. Cal. Apr. 10, 2013), a case involving claims concerning advertisements about a product's benefits to prostate health:

> Plaintiffs' arguments that the Prostate Claims are deceptive and/or misleading are confusing at best and rely on circular reasoning. For example, although Plaintiffs fervently argue that they do not have to prove that Bayer's representations are in fact false to proceed under the UCL and CLRA, Plaintiffs simultaneously argue that their "evidence is not limited to criticisms about the amount of substantiation Bayer had, but that the advertisements are not true." Thus, in an attempt to plead around the "lack of substantiation" bar to recovery, it appears Plaintiffs are alleging that Bayer's representations are deceptive because they are unsubstantiated. However, as stated above, Bayer's representations are not provably false, and private plaintiffs under the UCL and CLRA are prohibited from bring a "lack of substantiation" claim.

Johns, 2013 WL 1498965, at *48 (internal citations omitted). Judge Battaglia's reasoning is equally applicable here. Essentially, Plaintiff is arguing that the Label Claims could be

misleading because a jury could find that Defendants have not proven them to be literally true, which is little more than a "lack of substantiation" claim. Accordingly, Plaintiff cannot survive summary judgment by arguing that a jury could find that the Label Claims are false or misleading despite scientific evidence supporting those claims. *See generally In re GNC*, 789 F.3d at 509 ("[M]arketing statements that accurately describe the findings of duly qualified and reasonable scientific experts are not literally false."). To the extent *Mullins* holds otherwise, the Court declines to follow it.

In sum, when a plaintiff presents admissible expert testimony that scientific studies do not support an advertised claim, and a defendant presents admissible expert testimony that scientific studies support the advertised claim, the evidence is equivocal and all reasonable scientists do not agree. No jury conclusion would change either of these facts. The existence of studies supporting the advertisements would mean that a jury finding for the plaintiff has simply found that the evidence supporting one of two permissible judgments (namely, that the products do not work as advertised, or that they do) is more persuasive, but not that the advertisements themselves are literally false. *Cf. In re Rigel Pharm., Inc. Sec. Litig.*, 697 F.3d 869, 877 (9th Cir. 2012) ("In order to allege falsity, a plaintiff must set forth facts explaining why the difference between two statements is not merely the difference between two permissible judgments, but rather the result of a falsehood."). In such a circumstance summary judgment is appropriate. To hold otherwise would require a defendant to affirmatively prove the truth of, i.e., to substantiate,[4] its advertising claims to avoid liability for false advertising, which a private plaintiff is not allowed to require. As a result, regardless of whether a plaintiff's burden of proof is characterized as (1) all reasonable experts in the field agree that the representations are false, or (2) the evidence is unequivocal that the representations are false, a plaintiff cannot survive summary judgment when a defendant presents admissible expert testimony that

[4] One definition of substantiate is "to establish by proof or competent evidence." Webster's Ninth New Collegiate Dictionary (1983).

there is scientific support for the alleged misrepresentations. This is because the mere existence of such evidence makes it impossible for a jury to find that all reasonable experts agree or that the evidence is unequivocal that the advertising claims are false.

Having arrived at this determination, the Court must determine whether Defendants have offered any admissible evidence of scientific studies supporting the Label Claims. To do so, the Court must address Plaintiff's motions to exclude defense experts.

V. Motions to Exclude Experts

A. Legal Standards For Admissibility of Expert Testimony

Under Federal Rule of Evidence 702,

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

In determining the admissibility of expert testimony, "the Rules of Evidence—especially Rule 702—[] assign to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993). In other words, the Court must undertake a two-step assessment of whether: "(1) the reasoning or methodology underlying the testimony is scientifically valid (the reliability prong); and (2) whether the reasoning or methodology properly can be applied to the facts in issue (the relevancy prong)." *Johns*, 2013 WL 1498965, at *6.

"Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Daubert*, 509 U.S. at 591 (citation omitted). "District courts must strike the appropriate balance between admitting reliable, helpful expert testimony and excluding misleading or confusing testimony to achieve the flexible approach outlined in *Daubert*." *United States v. Cordoba*, 104 F.3d 225, 228 (9th Cir. 1997) (citation omitted).

The "test of reliability is 'flexible,' and *Daubert*'s list of specific factors neither necessarily nor exclusively applies to all experts or in every case." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999). "Shaky but admissible evidence is to be attacked by cross examination, contrary evidence, and attention to the burden of proof, not exclusion." *Primiano v. Cook*, 598 F.3d 558, 564 (9th Cir. 2010). "Under *Daubert*, the district judge is 'a gatekeeper, not a fact finder.' When an expert meets the threshold established by Rule 702 as explained in *Daubert*, the expert may testify and the jury decides how much weight to give that testimony." *Id*. at 564-65 (quoting *United States v. Sandoval-Mendoza*, 472 F.3d 645, 654 (9th Cir. 2006)). Put differently, "[t]he judge is supposed to screen the jury from unreliable nonsense opinions, but not exclude opinions merely because they are impeachable." *City of Pomona v. SQM N. Am. Corp.*, 750 F.3d 1036, 1044 (9th Cir. 2014) (internal quotation marks omitted).

B. Defense Expert Susan Mitmesser [Doc. Nos. 177, 183]

In her expert report, Dr. Susan Mitmesser provides the following summary of her opinions:

> I have thoroughly reviewed the scientific literature (including the references stated below) pertaining to gingko biloba and brain function. It is my professional opinion that the scientific evidence supports the claims stated on the product label (i.e., healthy brain function and circulation). Furthermore, the clinical evidence has been repeated in a variety of populations with numerous clinical endpoints which further adds to the conclusion that gingko biloba supports healthy brain function.

[Doc. No. 181-2 at 15.] Plaintiffs move to exclude the testimony of Dr. Mitmesser on the grounds that: (1) she is unqualified; (2) her opinions are unreliable; and (3) her opinions are not relevant.

1. Qualifications

Dr. Susan Mitmesser has a Masters of Science and a Ph.D. in Human Nutrition from the University of Nebraska. She was a clinical professor in the Department of Family Medicine at Stony Brook University from 2014 to 2016. She has also worked for The Nature's Bounty Co. as Director, Nutrition research, and then Senior Director, Nutrition &

Scientific Affairs, since 2012. Previously, she was Manager, Medical Communications, and then Manager, Global Medical Communications, at Mead Johnson Nutrition from 2005 to 2012. Her job responsibilities at Nature's Bounty and Mead Johnson included authoring and coordinating publication of peer-reviewed manuscripts based on clinical research and managing clinical study report development and nutrition research activities. Her resume lists dozens of peer-reviewed articles, book chapters, abstracts, and presentations where she was an author or presenter. [*Id.* at 29-35.] She is or has been on the editorial boards or committees of nine journals or organizations.

Notwithstanding the foregoing, Plaintiff argues that Dr. Mitmesser is unqualified to offer her opinions because she "has ***no pre-litigation experience***, training or education related to studies of substances on brain health (other than a very limited role in a study on smoking and brain function), and, most important, no experience with [Gingko biloba] in general or its effect/non-effect on brain health in particular." [Doc. No. 183-1 at 20 (*emphasis* in original).] This argument reflects a misunderstanding of Dr. Mitmesser's testimony and of the standards applicable to Plaintiff's false advertising claims. Dr. Mitmesser is not opining that Gingko biloba in fact provides the benefits advertised on the label; she is opining that scientific evidence exists to support the Label Claims. Thus, to offer an opinion on whether there is scientific support for the Label Claims, Dr. Mitmesser need not already have experience with Gingko biloba or brain health studies. Rather, she needs to be qualified to review the available scientific evidence and offer an opinion on what that evidence reveals. As a doctor of nutrition with extensive experience reviewing studies on the effects of nutritional products based on clinical studies and research, she is qualified to offer an opinion, based on her assessment of the clinical studies and research on Gingko biloba, as to whether such studies support the Label Claims.

2. Reliability

Plaintiff next argues that "Dr. Mitmesser's opinions are unreliable because they contravene not just one – but numerous material, well-established scientific principles and methodologies and employed by experts in the field." [Doc. No. 183-1 at 21.] Once again,

however, this argument is premised on a mischaracterization of Dr. Mitmesser's opinions. Plaintiff argues that Dr. Mitmesser does not base her opinions on a "totality of the evidence" analysis, but Dr. Mitmesser is not offering an opinion as to whether Gingko biloba actually works as advertised or even whether the "totality of the evidence" supports the Label Claims. Rather, Dr. Mitmesser is simply opining that there is scientific evidence that supports those claims. That there may be other scientific evidence that casts doubt on the Label Claims does not render her opinion unreliable or inadmissible.

Plaintiff's argument that Dr. Mitmesser's opinions are unreliable because "[s]he ignores the limits on extrapolating from studies of diseased patients to healthy populations observed by experts in the field – and as set forth in FDA guidelines to dietary supplement manufactures," [Doc. No. 183-1 at 23] is misplaced for the same reason. Dr. Mitmesser opines that scientific evidence supports the Label Claims. Neither the Label Claims nor the class definition are limited to healthy people not suffering from any disease. Plaintiff's position in this case, as reflected in her motion for class certification, is that Gingko biloba provides no benefit to anyone, regardless of whether they are diseased or healthy, old or young. The existence of studies on diseased patients would therefore support Dr. Mitmesser's opinion and the Label Claims, and contradict Plaintiff's argument that Gingko biloba provides no benefit to anyone. That the Label Claims are not false for some purchasers precludes a finding of liability on a classwide basis and entitles Defendants to summary judgment. *See Rikos v. Procter & Gamble Co.*, 799 F.3d 497, 520 (6th Cir. 2015), cert. denied, 136 S. Ct. 1493, 194 L. Ed. 2d 597 (2016) (holding that evidence that a product has been proven to work for some individuals is not fatal to a predominance determination on class certification in case where the plaintiff's theory of liability was that the product was worthless, but noting that "the more straightforward impact of this evidence is simply that it may prevent Plaintiffs from succeeding on the merits," because

"if [the product] is shown to work, even for only certain individuals, then presumably Plaintiffs lose.").[5]

It is particularly notable that Plaintiff does not (and cannot) argue that the studies on which Dr. Mitmesser relies were not studies on Gingko biloba, or that the studies did not conclude that Gingko biloba provided some positive effect. Dr. Mitmesser's export report lists numerous studies on which she relied for her opinion, along with her brief summary of each study and its results and how the study provides evidence for the benefits of Gingko biloba. The publications of these studies include statements such as:

- "The results show that *Ginkgo biloba* extract gave sustained and protracted improvements of all the tested symptoms of cerebral insufficiency [which included vertigo, headache, tinnitus, short-term memory, vigilance, and mood]. These good therapeutic results may possibly be explained by an improvement in global and regional blood-flow in the brain, with an increase in oxygen and glucose utilization." G. Vorberg, *Gingko Biloba Extract (GBE*): A Long-Term Study of Chronic Cerebral Insufficiency in Geriatric Patients*, Clinical Trials Journal Vol. 22, No. 2 (1985) [Doc. No. 172-4 at 9.]
- "The results show that chronic [Gingko biloba] medication has a positive effect in geriatric subjects with deterioration of mental performance and

[5] Plaintiff's new position on summary judgment that the issue in this case is "whether [Gingko biloba] provides brain health benefits to healthy persons," [Doc. No. 199 at 6] is contradicted by the Labels themselves, which do not limit the brain health claims to "healthy persons," and by the class definition sought by Plaintiff, and certified by the Court, which includes all purchasers of TruNature Gingko, not just healthy purchasers. Plaintiff's new argument also cannot be reconciled with her argument in support of class certification that Plaintiff intended to prove that "the TruNature products do not provide any brain health benefits making them worthless to anyone who takes them," [Doc. No. 116 at 8.] and that "because the TruNature Product is worthless, Plaintiff and the Class members are entitled to receive the total retail price they paid." [Doc. No. 107 at 32.] It was this argument that caused the Court to hold that class certification was warranted because "[t]he answer to these questions will be the same for the entire class. Likewise, the determination of whether the statements on the label are material and likely to deceive a reasonable consumer will be the same for the entire class." [Doc. No. 158 at 10.] Studies showing that Gingko biloba provides benefits to diseased persons directly undermine the "theory of the case" Plaintiff advocated on class certification.

vigilance, and this effect is reflected at the behavioural level." B. Gebner et al., *Study of the Long-term Action of a Gingko biloba Extract on Vigilance and Mental Performance as Determined by Means of Quantitative Pharmaco-EEG and Psychometric Measurements*, Arzneim-Forsch/Drug Res. 35 (II), Nr. 9 (1985) [Doc. No. 181-2 at 3.]

- "[Gingko biloba] was safe and appears capable of stabilizing and, in a substantial number of cases, improving the cognitive performance and the social functioning of demented patients for 6 months to 1 year." P. LeBars et al., *A Placebo-Controlled, Double-blind, Randomized Trial of an Extract of Gingko biloba for Dementia*, JAMA, October 22/29, 1997—Vol 278, No. 16 [Doc. No. 172-9 at 2.]
- "Overall, [Gingko biloba] appears to have improved cognitive performance and social functioning when the treatment group included a majority of patients with very mild to mild cognitive impairment." P. LeBars et al., *Influence of the Severity of Cognitive Impairment on the Effect of the* Gingko biloba *Extract EGb 761 in Alzheimer's Disease*, Neuropsychobiology 2002; 45:19-26 [Doc. No. 181-4 at 7.]
- "[Gingko biloba tablet] can improve the therapeutic efficacy as well as improve cognitive ability and cerebral blood flow supply of patients with [vascular cognitive impairment of none dementia]." S. Zhang et al., *Effect of Western Medicine Therapy Assisted by Gingko biloba Tablet on Vascular Cognitive Impairment of None Dementia*, Asian Pacific Journal of Tropical Medicine (2012), 661-664 [Doc. No. 172-12 at 2.]
- "Statistical analysis of the data as compared to baseline suggests that Gingko biloba extract had a beneficial effect on cognitive function in this group of patients." G.S. Rai et al., *A Double-blind, Placebo-controlled study of* Gingko biloba *Extract ('Tanakan') in Elderly Out-patients with Mild to*

Moderate Memory Impairment, Current Medical Research and Opinion, Vol. 12, No. 6 (1991) [Doc. No. 181-5 at 2.]

- "The findings of the present study are that Tanakan [Gingko biloba] produced favourable effects on the mental efficiency of elderly non-institutionalized patients." K. Wesnes et al., *A Double-blind Placebo-controlled Trial of Tanakan in the Treatment of Idiopathic Cognitive Impairment in the Elderly*, Human Psychopharmacology, Vol. 2, 159-169 (1987) [Doc. No. 181-9 at 10.]

In other words, Dr. Mitmesser's opinion that there is scientific support for the Label Claims about the benefits of Gingko biloba is based on published scientific studies where the authors conclude that Gingko biloba had positive effects in ways that support the Label Claims. Moreover, Dr. Mitmesser's testimony "is based directly on legitimate, preexisting research unrelated to the litigation." *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) (noting that testimony based on preexisting research "provides the most persuasive basis for concluding that the opinions he expresses were 'derived by the scientific method'"). That other contradictory research may exist or that the research on which Dr. Mitmesser relies has methodological flaws that make it less persuasive (in Plaintiff's view) of the efficacy of Gingko biloba goes to the weight of Dr. Mitmesser's opinion, not its admissibility. *See Kennedy v. Collagen Corp.*, 161 F.3d 1226, 1231 (9th Cir. 1998) ("Disputes as to the strength of an expert's credentials, faults in his use of a particular methodology, or lack of textual authority for his opinion, go to the weight, not the admissibility, of his testimony.") (internal brackets and citation omitted). Accordingly, Dr. Mitmesser's testimony is sufficiently reliable.

3. Relevance

Finally, Plaintiff argues that Dr. Mitmesser's opinions are irrelevant "because they are based on her incorrect belief that Defendants' TruNature GB brain health claims need not be scientifically proven." [Doc. No. 183-1 at 25.] Once again, Plaintiff's premise is flawed. Indeed, this argument undermines Plaintiff's entire opposition to summary

judgment because it effectively serves as an acknowledgement that Plaintiff's claims are based on Defendants' alleged inability to scientifically prove (i.e., "substantiate") the Label Claims. If, as Plaintiff argues, Dr. Mitmesser's opinion is irrelevant to Plaintiff's claims because the issue for a jury is whether the Label Claims are scientifically proven, then this case is nothing more than a lack of substantiation case.[6] Plaintiff even relies on FDA guidelines for substantiation of product benefit claims by supplement manufactures in making this argument. [Doc. No. 183-1 at 9-10.] Yet, as discussed above, California does not allow private actions based on a lack of substantiation. Accordingly, Plaintiff's entire line of reasoning for why Dr. Mitmesser's opinions are irrelevant is misplaced and demonstrates why Defendants are entitled to summary judgment.

Ultimately, Dr. Mitmesser's opinions relate to the question of whether Plaintiff can prove that the Label Claims are false. Plaintiff cannot prove the Label Claims are false if scientific evidence supporting the claims exists. Dr. Mitmesser is qualified to review the research on the efficacy of Gingko biloba and offer an opinion as to what that research concludes, including whether the research supports the Label Claims. Her reasoning is valid and her opinions are relevant to the issues in this case. Therefore, Plaintiff's motion to exclude Dr. Mitmesser's opinions and testimony is denied.

C. Defense Expert Edward Rosick [Doc. Nos. 178, 184]

Dr. Rosick's opinion is similar to Dr. Mitmesser's: "what the research and science shows is that there is reasonable evidence that gingko biloba is a very safe herbal supplement that can promote healthy brain function, improve memory and attention, and help promote healthy circulation." [Doc. No. 182-1 at 13.] He bases this opinion on some of the same studies and research cited by Dr. Mitmesser as well as other studies. Dr. Rosick also critiques the studies on which Plaintiff's experts rely.

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[6] In her reply, Plaintiff implies that the burden shifts to Defendants because Plaintiff offered expert testimony based on studies that do not support the Label Claims. [Doc. No. 199 at 2.] Plaintiff does not cite to any authority for a burden shifting scheme, and such a scheme would render California's bar on lack of substantiation claims effectively meaningless.

Plaintiff's motion for exclusion of Dr. Rosick's opinion testimony makes many of the same arguments as the motion to exclude Dr. Mitmesser: (1) that he is not qualified; (2) that his opinions are not reliable; and (3) that his opinions are irrelevant because he does not use the totality of the evidence standard that Plaintiff incorrectly argues applies to her claims. For many of the same reasons discussed above with respect to Dr. Mitmesser, the Court disagrees and finds Dr. Rosick's opinions to be admissible.

As for his qualifications, Dr. Rosick is a physician with a degree from the Michigan State University College of Osteopathic Medicine. Since graduating in 1993 he has held numerous roles at Michigan State, including Clinical Assistant Professor of Medicine, Associate Professor in the College of Osteopathic Medicine, and Medical Director of the Family and Community Medicine Clinic in the College of Osteopathic Medicine. He is Board Certified in Preventive Medicine, Public Health and Integrative Medicine, and has been on the medical staff of various medical centers continually since at least 1998. Based on his education and experience as a practicing physician and teaching at a medical school, Dr. Rosick is qualified to offer his opinions about the existence of research and scientific evidence supporting the Label Claims.

Dr. Rosick's opinions are also sufficiently reliable and relevant for the same reasons as discussed above with respect to Dr. Mitmesser's opinions. Plaintiff's arguments about the quality of the studies on which Dr. Rosick relies goes to the weight of his testimony, not its admissibility. Likewise, his opinions about the existence of scientific research supporting the Label Claims are relevant to an issue in this case—whether Plaintiff can prove that the Label Claims are false. Further, Plaintiff's argument that Dr. Rosick does not provide the bases for his opinion about what the scientific research and evidence shows is puzzling in light of the fact that he cites to the scientific articles and research on which he relies in his report and attached copies of the studies not also referenced by Dr. Mitmesser to his declaration in support of Defendants' motion for summary judgment. [Doc. Nos. 172-22 – 172-30.] Once again, Plaintiff does not (and cannot) argue that the studies and articles on which Dr. Rosick relies were not about the efficacy of Gingko

biloba, or that the studies and articles did not conclude that Gingko biloba provided some positive effect. In addition to many of the same studies cited by Dr. Mitmesser, the studies and reports on which Dr. Rosick relies include statements such as:

- "There is consistent evidence that chronic administration improves selective attention, some executive processes and long-term memory for verbal and non-verbal material." R. Kaschel, *Ginkgo biloba: Specificity of Neuropsychological Improvement—a Selective Review in Search of Differential Effects*, Human Psychopharmacology (2009) [Doc. No. 172-26 at 2.][7]
- "Taken together, the results from both the objective, standardized, neuropsychological tests and subjective Follow-up Self-report Questionnaire provided complementary evidence of the potential efficacy of relatively short-term (i.e. 6 weeks) utilization of [Gingko biloba extract] in enhancing certain neurocognitive/memory functions of cognitively intact older adults, 60 years

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[7] Notably, this review acknowledges that the research has not uniformly found that Gingko biloba has positive effects:

> A first Cochrane meta-analysis including 33 randomized placebo-controlled trials found superiority over placebo in different domains: cognition, activities of daily living as well as mood and emotional functions in dementia and other cognitive disorders. There was 'promising evidence of improvement in cognition and function associated with gingko' (Birks *et al.*, 2002; p.2). This is in line with another review which stated that its use in dementia is 'encouraging' (Ernst and Pitller, 1999; p. 301) and the conclusion that 'for treating cognitive impairment and dementia, the evidence suggests that gingko is effective' (Ernst *et al.*, 2006; p. 404). Although relating to a similar database, an updated Cochrane review is more skeptical: 'There is no convincing evidence that Gingko biloba is efficacious for dementia and cognitive impairment . . . Evidence that Gingko has predictable and clinically significant benefit for people with dementia or cognitive impairment is inconsistent and unconvincing.

[Doc. No. 172-26 at 3.] In a separate article, the same author similarly acknowledges that "[b]oth positive and negative findings have been reported from trials using other Ginkgo biloba leaf extracts in healthy young as well as in elderly persons." [Doc. No. 172-28 at 3.] The fact that there is a difference of opinion among scientists and that studies have yielded varying results as to Gingko biloba's efficacy means that Plaintiff cannot prove that the Label Claims are false. *See Reed*, 2014 WL 12284044, at *15.

of age and over. . . . The present study's findings appeared consistent with past studies that have demonstrated the efficacy of *Gingko biloba* extract for the treatment of dementia and 'cerebral insufficiency.' . . . The results also bolster those from the few previously published, small-scaled studies that have found improvements in cognitive functioning among older cognitively intact adults . . . and young, healthy volunteers." J. Mix and W. Crews, *A Double-blind, Placebo-Controlled, Randomized Trial of* Gingko biloba *Extract EGb 761® in a Sample of Cognitively Intact Older Adults: Neuropsychological Findings*, Human Psychopharmacology (2002) [Doc. No. 172-27 at 9-10.]

- "[Gingko biloba extract] EGb 761 (240 mg once daily) improves free recall of appointments in middle-aged healthy volunteers, which requires high demands on self-initiated retrieval of learned material." R. Kaschel, *Specific Memory Effects of Gingko biloba Extract EGb 761 in Middle-Aged Healthy Volunteers*, Phytomedicine 18 (2011) 1202-1207. [Doc. No. 172-28 at 2.]

In other words, as with Dr. Mitmesser's opinion, Dr. Rosick's opinion that "research and science shows [] that there is reasonable evidence that gingko biloba . . . can promote healthy brain function, improve memory and attention, and help promote healthy circulation" is based on published scientific research and review articles where the authors conclude that Gingko biloba had such positive effects on study participants. This testimony is sufficiently reliable and relevant to the issue of whether Plaintiff can prove that the Label Claims are false. Accordingly, the motion to exclude Dr. Rosick is denied.

D. Defense Expert Stephen Ogenstad [Doc. No. 176], and Plaintiff's Experts Richard Bazinet and Martin Lee [Doc. No. 173]

Because the Court ultimately concludes that Defendants are entitled to summary judgment regardless of the admissibility of defense expert Stephen Ogenstad and Plaintiff's experts Richard Bazinet and Martin Lee, the motions to exclude those experts are denied as moot.

E. Defendants' Request for Judicial Notice [Doc. No. 172-56] /Plaintiff's Motion to Strike Evidence [Doc. No. 191]

Because Defendants are entitled to summary judgment regardless of the admissibility of the evidence of which they seek judicial notice and that Plaintiff seeks to strike, the Court did not consider any of the web pages and other documents at issue in the request and motion to strike. Accordingly, Defendants' request for judicial notice [Doc. No. 172-56] and Plaintiff's motion to strike [Doc. No. 191] are both denied as moot.

VI. Analysis

Having determined that under California law a Plaintiff cannot maintain a false advertising claim when the defendant offers admissible expert testimony and scientific evidence supporting the advertisement in question, and that Dr. Mitmesser's testimony and Dr. Rosick's testimony are both admissible, the application of the law to the facts here is relatively simple. In short, the existence of admissible expert testimony that scientific studies and evidence supports the Label Claims is fatal to Plaintiff's case. To hold otherwise and allow a jury to weigh the strength of Defendants' scientific support simply because Plaintiff intends to offer scientific evidence of her own would effectively mean that all a Plaintiff needs to circumvent California law barring lack of substantiation claims is one scientific study that does not support the alleged misrepresentations.[8]

Plaintiff concedes, as she must, that there are some studies demonstrating that Gingko biloba might work. [Doc. No. 183-1 at 6.] "When litigants concede that some reasonable and duly qualified scientific experts agree with a scientific proposition, they cannot also argue that the proposition is literally false." *In re GNC*, 789 F.3d at 515. Even Plaintiff's expert Dr. Bazinet, on whom Plaintiff relies extensively for her claims, does not opine that the Label Claims are literally false based only on the existence of a handful of studies that did not yield positive results, particularly in light of the dozens of studies cited

[8] Plaintiff essentially took this position at oral argument, asserting that even if 90% of the evidence supported the Label Claims, this case should go to the jury.

by the defense experts. Instead, when reading his report as a whole, his opinion simply amounts to a conclusion that because Gingko biloba studies finding no positive results are better studies than those finding positive results, the "totality of the evidence" does not support the Label Claims. Notably, Dr. Bazinet did not consider evidence of studies on diseased subjects that showed positive results of Ginkgo biloba, despite the fact that the class is not limited to non-diseased individuals. [Doc. No. 173-3 at ¶ 16.] Moreover, that he frames his opinion as based on the "totality of the evidence," and acknowledges that "there are some earlier positive trials," [*Id.* at ¶ 28], means that Dr. Bazinet is not opining that there is no evidence or scientific research supporting the Label Claims or that the evidence is unequivocal that the Label Claims are false. Dr. Bazinet's criticisms of the methodology used in the studies on which Defendants rely does not nullify the existence of those studies.[9]

In reality, however, whether Plaintiff concedes that there are studies supporting the Label Claims is irrelevant in light of the host of studies cited by Defendants' experts. Dr. Bazinet's opinion, and Plaintiff's argument, that the methodological flaws in the studies on which Defendants' experts rely render those studies weaker than the studies on which Plaintiff relies do not eliminate the equivocality of the evidence concerning the Label Claims. There can be no genuine dispute of fact that such studies exist or that they conclude that Gingko biloba provided health and memory benefits. The only dispute articulated by

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[9] False advertising claims like Plaintiff's that argue the active ingredient in a product provides no health benefits are distinguishable from claims that advertisements about the benefits of a product are misleading because the amounts of the active ingredient in the product are too small to be bioavailable, meaning that the product in question cannot provide the benefit that its active ingredient might provide in larger doses. Other cases have made this distinction between variations of allegedly false efficacy claims. *See, e.g., Racies v. Quincy Bioscience, LLC*, Case No. 15-cv-00292-HSG, 2015 WL 2398268, at *3-4 (N.D. Cal. May 19, 2015) (dismissing claims that representation was false because "no competent and reliable studies testing the Product exist," while denying motion to dismiss claims that the product cannot work as represented because the active ingredient "is destroyed by the human digestive system or is of such a trivial amount that it cannot biologically affect memory or support brain function"). Plaintiff makes no such argument here and many of the studies cited by Dr. Mitmesser and Dr. Rosick test Gingko biloba in similar or identical dosages to those contained in TruNature Gingko.

Plaintiff is whose studies and whose experts are better. Yet a jury finding by a preponderance of the evidence that Plaintiff's experts are more persuasive does not equal a finding that the Label Claims are literally false, or that they are true but otherwise misleading. Because there is no dispute of fact that there is scientific evidence both supporting and contradicting the Label Claims, the evidence is equivocal and Defendants are entitled to summary judgment.

VII. Conclusion

In light of the foregoing, it is hereby **ORDERED** as follows:

1. CRN's motion to file a brief amicus curiae [Doc. No. 187] is **GRANTED**;
2. Plaintiff's motions to exclude the testimony of Susan Mitmesser [Doc Nos. 177, 183] and Edward Rosick [Doc. Nos. 178, 184] are **DENIED**;
3. Plaintiff's motion to exclude the testimony of Stephen Ogenstad [Doc. No. 176] is **DENIED AS MOOT**;
4. Defendants' motion to exclude the testimony of Richard Bazinet and Martin Lee is [Doc. No. 173] is **DENIED AS MOOT**;
5. Defendants' request for judicial notice [Doc. No. 172-56] and Plaintiff's motion to strike [Doc. No. 191] are **DENIED AS MOOT**; and,
6. Defendants' motion for summary judgment [Doc. No. 172] is **GRANTED**.

Accordingly, the Clerk of Court is instructed to enter **JUDGMENT** for Defendants and to **CLOSE** this case.

It is **SO ORDERED**.

Dated: August 23, 2017

Hon. Cathy Ann Bencivengo
United States District Judge